

REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed November 14, 2007 and entry of the present amendment is requested because Applicants respectfully submit that the present Amendment places the application in condition for allowance or in better form for consideration on appeal.

In response to the Final Office Action, claims 1-10, 19, 20, 27, and 28 have been canceled without prejudice (for consideration in a future divisional application), claims 11 and 25 have been amended, and new claims 29-38 have been added. Support for the amendments may be found, for example, between page 71, line 23, and page 72, line 18, in the paragraphs at page 75, lines 3-23, between page 78, line 20 and page 79, line 10, and at page 79, lines 7-10, as well as by the original claims. No new matter has been introduced. Therefore, claims 11-14, 16-18, 25-26, and 29-38 are currently pending.

In the Final Office Action, claims 11-14, 16, 17, 25, and 26 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,994,686 (“the Cruise et al. reference”) in view of U.S. Patent No. 6,223,936 (“the Jeanbourquin reference”). Because neither of the cited references, either alone or in combination disclose, teach, or suggest the subject matter of the present claims, the rejections should be withdrawn.

As an initial matter, Applicants appreciate the Examiner’s indication that claim 18 remains allowed.

With respect to the Cruise et al. reference, a system is disclosed for sealing a vascular puncture site. Col. 5, lines 8-10. In one embodiment, the system includes an access assembly 16 including a catheter device 20 and a barrier material introducer/mixer 22, and a barrier component

assembly 18 to house the components of the fluid barrier material prior to use. Col. 5, lines 22-231. The Cruise et al. systems involve double syringe delivery systems that are manually operated to deliver fluids out of syringe barrels.

Turning to the present claims, claim 11 recites a method for delivering a sealing compound from a delivery device comprising a pair of barrels including outlets and a plunger assembly slidable within the barrels from a first position to a second position for injecting components out of the barrels through the outlets that includes introducing a delivery sheath into a puncture through tissue; connecting the barrels to a lumen of the delivery sheath; providing sealing components in the barrels with the plunger assembly in the first position; and activating an actuator coupled to a spring mechanism to release the spring mechanism, whereupon the spring mechanism automatically directs the plunger assembly towards the second position to inject the sealing components out of the barrels through the lumen of the delivery sheath and into the puncture without pauses during delivery of the components out of the barrels.

The Cruise et al. reference does not disclose, teach, or suggest activating an actuator coupled to a spring mechanism to release the spring mechanism, whereupon the spring mechanism automatically directs the plunger assembly towards the second position to inject the sealing components out of the barrels through the lumen of the delivery sheath and into the puncture without pauses during delivery of the components out of the barrels. In fact, the Cruise et al. reference fails to teach or suggest anything about auto-injector assemblies, as conceded in the Final Office Action.

The Jeanbourquin reference fails to disclose, teach, or suggest this step that is also wholly absent from the Cruise et al. reference. Instead, the Jeanbourquin reference discloses a device for

simultaneously delivering fluids from two containers. Col. 1, lines 9-10. The device includes two syringe bodies 4a, 4b fixed to a carrier 10 and a grip 20. Col. 2, lines 13-24. A slider 30 is slidably mounted to the carrier 10 and is displaced proximally by a spring 32 unless prevented by braking surface 41. Col. 2, lines 38-44. A brake lever 40 is urged by a spring 50 resulting in the braking surface 41 being urged against the slider 30. Col. 2, lines 55-59. During use, the brake lever 40 is pulled to a grip 20 against the force of the spring 50, thereby reducing the effect of the braking surface 41 on the slider 30 and the slider is shifted by spring 32. Col. 2, line 65 to col. 3, line 2. To prevent accidental actuation of the brake lever, a locking mechanism 60 is applied between the brake lever 40 and the grip 20. Col. 3, lines 9-11.

The Jeanbourquin reference discloses two springs, neither of which is released when an actuator is activated. One Jeanbourquin spring 50 is provided between a brake lever 40 and a grip 20 that may be compressed when a user pulls the brake lever 40 towards the grip 20 to release a braking surface. When the brake lever is released, the spring biases the braking surface to engage a slider to stop fluid delivery from the barrels. Thus, this spring has nothing to do with directing pistons to deliver components out of barrel chambers, and in fact prevents such delivery.

The other Jeanbourquin spring 32 constantly urges a slider to move proximally relative to a carrier, but the urge is resisted by a braking surface 41 unless the brake lever 40 is pulled towards the grip 20. Thus, this spring is not *released* once an actuator is activated to *automatically* direct pistons towards their distal position to deliver components out of barrel chambers. Instead, the Jeanbourquin brake lever may be pulled and released to selectively deliver fluids from syringe barrels. Specifically, if a user pulled the brake lever for a short time and then

released it, fluid would stop flowing from the syringe barrels because the braking surface 41 would again engage the slider 30.

Thus, the Jeanbourquin reference does not teach or suggest a spring mechanism that automatically directs the plunger assembly towards the second position to inject the sealing components out of the barrels through the lumen of the delivery sheath and into the puncture *without pauses during delivery of the components out of the barrels*, as claimed.

In contrast to the Jeanbourquin device, one of the advantages of the claimed auto-injection assembly is that it *automatically* delivers components, such as sealing components, from barrels without unintended pauses. As explained at page 79, lines 3-7 of the present application “Such interruptions risk occluding the delivery line, i.e., the ‘Y’ fitting, mixer, or other passages through which the sealing compound passes. This may be a particular concern where the sealing compound has a relatively short gel or set-up time.” The Jeanbourquin reference fails to address this concern and would actually exacerbate this problem, because the disclosed device is biased to stop delivery. Even if there somehow was motivation to provide sealing components in the Jeanbourquin device, which Applicants do not concede, the device risks occluding a delivery line, because the device is biased to stop fluid flow when the user releases the brake lever and cannot automatically deliver fluid. For these reasons, claim 11 and its dependent claims are neither anticipated by nor otherwise obvious over the Jeanbourquin reference.

For similar reasons, claim 25 and 33, and their dependent claims are also neither anticipated by nor otherwise obvious over the Jeanbourquin reference. Similar to claim 11, claim 25 recites activating an actuator coupled to a spring mechanism to release the spring mechanism, whereupon the spring mechanism automatically directs the plunger assembly towards the second

position to inject the sealing components out of the barrels into the puncture *at a substantially continuous rate*. Neither of the cited references discloses, teaches, or suggest a spring mechanism that automatically directs the plunger assembly towards the second position to inject the sealing components out of the barrels into the puncture at a substantially continuous rate. Claim 33 also recites a spring mechanism that automatically directs the plunger assembly towards the second position to inject the sealing components out of the barrels into the puncture without pauses during delivery of the components out of the barrels.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,
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